UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Bey 1459.

P O Box 1450 Alexandria, Virgima 22313-1450 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26389 7590 09/10/2009

CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC 1420 FIFTH AVENUE SUITE 2800

SEATTLE, WA 98101-2347

EXAMINER

IOHANNSEN DIANA R

ART UNIT PAPER NUMBER

1634 DATE MAILED: 09/10/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,007	09/25/2003	Wendy H. Raskind	UWOTL121680	8123

TITLE OF INVENTION: METHODS FOR IDENTIFYING SUBJECTS SUSCEPTIBLE TO ATAXIC NEUROLOGICAL DISEASE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	12/10/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE: shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

appropriate. All further indicated unless correct maintenance fee notifica	ed below or directed otl	ng the Patent, advance on nerwise in Block 1, by (rders and notification a) specifying a new of	corres	pondence address;	and/or	(b) indicating a sepa	arate "I	FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.					
1420 FIFTH AV SUITE 2800	ENUE	¹²⁰⁰⁹ JOHNSON, KIND	NESS, PLLC	I her State addr trans	Cer reby certify that the es Postal Service we essed to the Mail smitted to the USP	tificate is Fee(: /ith suf Stop TO (57	of Mailing or Trans s) Transmittal is being ficient postage for fir ISSUE FEE address I) 273-2885, on the d	mission g depos st class above, late ind	n sited with the United mail in an envelope , or being facsimile icated below.
SEATTLE, WA	98101-2347								(Depositor's name)
				\vdash					(Signature)
				ᆫ					(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVE	NTOR		ATTO	RNEY DOCKET NO.	CON	FIRMATION NO.
10/671,007 TITLE OF INVENTION	09/25/2003 I: METHODS FOR IDE	NTIFYING SUBJECTS S	Wendy H. Raskii SUSCEPTIBLE TO A		IC NEUROLOGIC		WOTL121680 SEASE		8123
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE	DUE	PREV. PAID ISSUE	S FEE	TOTAL FEE(8) DUE		DATE DUE
nonprovisional	YES	\$755	\$300		\$0		\$1055		12/10/2009
EXAM	IINER	ART UNIT	CLASS-SUBCLAS	s					
JOHANNSE	N, DIANA B	I634	435-006000						
"Fee Address" ind PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A	ondence address (or Cha B/122) attached. ication (or "Fee Address)2 or more recent) attack ND RESIDENCE DATA	inge of Correspondence	(I) the names of or agents OR, alte (2) the name of a registered attorne 2 registered paten listed, no name w	up to ernative single y or a it attor ill be or typ	e firm (having as a gent) and the nam meys or agents. If printed.	memb es of u no nam	er a 2 o to e is 3	locume	nt has been filed for
Please check the appropriate (a) The following fee(s) I ssue Fee	iate assignee category or	categories (will not be po		(Plea	Individual 🚨 Co	orporati			
☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies			Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).						
	s SMALL ENTITY state	as. See 37 CFR 1.27.					TITY status. See 37 C		
interest as shown by the	records of the United Sta	uired) will not be accepte tes Patent and Trademark	Office.	uran u	ne applicant, a regi	stereu a	ittorney or agent; or ti	ic assig	nice of outer party in
Authorized Signature					Date				
Typed or printed name					Registration N				
This collection of inform an application. Confiden submitting the complete this form and/or suggest Box 1450, Alexandria, V Alexandria, Virginia 223	nation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this bu 'irginia 22313-1450. DO k13-1450.	CFR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	on is required to obtain 1.14. This collection of depending upon the e Chief Information COMPLETED FORM	in or r is est indiv Office AS TO	etain a benefit by t imated to take 12 i idual case. Any co r, U.S. Patent and D THIS ADDRESS	he publ minutes mment Traden i. SENI	ic which is to file (an- to complete, includir s on the amount of ti- nark Office, U.S. Dep D TO: Commissioner	I by the ng gathe me you artment for Pate	e USPTO to process) ering, preparing, and require to complete t of Commerce, P.O. ents, P.O. Box 1450,

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P O Box 1450 Alexandra, Virgima 22313-1450 www.uspto.gov

DATE MAILED: 09/10/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/671,007	09/25/2003	Wendy H. Raskind	UWOTL121680	8123	
26389 75	590 09/10/2009		EXAM	IINER	
CHRISTENSEN	, O'CONNOR, JOHN	JOHANNSEN, DIANA B			
1420 FIFTH AVENUE			ART UNIT	PAPER NUMBER	
SUITE 2800 SEATTLE WA 98	R101-2347		1634		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 316 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 316 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.	Applicant(s)				
10/671,007	RASKIND ET AL.				
Examiner	Art Unit				
Diana B. Johannsen	1634				

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative

- of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to the RCE of July 1, 2009.
- The allowed claim(s) is/are 1,2,4-6 and 43-46.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) \square All b) ☐ Some* c) ☐ None of the:
 - 1. T Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No.
 - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6.

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. | Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08). Paper No./Mail Date
- 4. T Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application Interview Summary (PTO-413),
- Paper No./Mail Date
- 7.

 Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- 9. ☐ Other .

Application/Control Number: 10/671,007 Page 2

Art Unit: 1634

ATTACHMENT TO NOTICE OF ALLOWABILITY

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2009 has been entered, resulting in the entry of the claim amendments originally filed June 1, 2009. Claim 1 has been amended. Claims 1-2, 4-6, and 43-46 are now allowed for the reasons indicated below.

 In accordance with 37 C.F.R. 1.126, allowed claims 1-2, 4-6, and 43-46 will be renumbered as claims 1-9, respectively (see MPEP 608.01(i)).

Withdrawal of species election

- 3. Independent claim 1 is now an allowed claim. Accordingly, upon further consideration and in view of the amendment of claim 1 and the allowability of that claim, the restriction requirement with respect to dependent claims 43-44, as set forth in the Office action mailed on August 30, 2007, is hereby withdrawn.
- 4. In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Application/Control Number: 10/671,007 Page 3

Art Unit: 1634

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Art Unit: 1634

5. The following is an examiner's statement of reasons for allowance:

As discussed previously in, e.g., the Office action of September 10, 2008, the data in the specification establishes the existence of multiple mutations in the PRKCG gene that are associated with adult onset cerebellar ataxia in different groups of human individuals, as well as other mutations in that gene for which a disease association is not yet clearly established. The claims have been amended such that they merely require "screening" for disease associated mutations by comparing a PRKCG gene sequence of a human individual with adult onset cerebellar ataxia with instant SEQ ID NO: 3 to identify differences that alter the amino acid sequence of human protein kinase C gamma, and performing cosegregation analysis to determine whether an identified mutation is disease associated. The guidance provided in the specification enables the practice of such methods. Further, the prior art does not teach or suggest the methods of the claims, which require a step of comparing a first nucleic acid sequence of a human PRKCG gene from a "human subject exhibiting adult onset cerebellar ataxia" with SEQ ID NO: 3 "to identify a difference" which alters the amino acid sequence encoded by the gene. It is again noted that the Declaration under 35 USC 1.132 filed December 12, 2008 established the Chen et al reference as being applicant's own work. Brkanac et al (Arch Neurol 59:1291 [August 2002]; cited in the IDS of May 2007) disclose the mapping of an SCA14 locus to chromosome 19g13.4-gter (see entire reference). However, Brkanac et al teach that this region encompasses "more than 250 genes" and that analysis of additional families will be needed to identify a target gene (see page 1295, left column); accordingly, given the teachings of the prior art, an

Application/Control Number: 10/671,007

Art Unit: 1634

ordinary artisan could not have predicted the existence of mutations such as those exemplified by applicants, and further would not have had a reasonable expectation that a method comprising step 1(b) could be performed successfully in screening for mutations associated with adult onset cerebellar ataxia in humans.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571/272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/671,007 Page 6

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/ Primary Examiner, Art Unit 1634